

CLAIMS

1. A membrane or matrix for controlling the permeation rate of a drug, said membrane or matrix comprising a siloxane-based elastomer composition comprising at least one elastomer and possibly a non-crosslinked polymer, characterized in that the elastomer composition comprises
 5 poly(alkylene oxide) groups, and that the poly(alkylene oxide) groups are present in the elastomer or polymer as alkoxy-terminated grafts of polysiloxane units, or as blocks, the said grafts or blocks being linked to the
 10 polysiloxane units by silicon-carbon bonds, or as a mixture of these forms.

2. The membrane or matrix according to Claim 1, characterized in that the elastomer composition is an elastomer made up of polysiloxane units which comprise poly(alkylene
 15 oxide) groups.

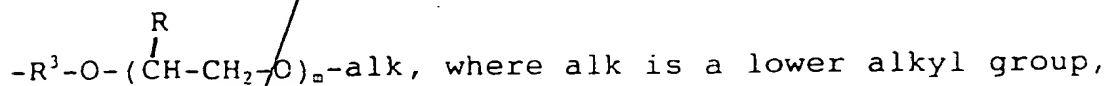
3. The membrane or matrix according to Claim 1 or 2, characterized in that the poly(alkylene oxide) groups are poly-(ethylene oxide) groups (PEO groups).

4. The membrane or matrix according to Claim 2 or 3, characterized in that the formula of the polysiloxane groups is
 20



where R' and R'' are

- partly free groups, which are the same or different and which are a lower alkyl group, or a phenyl group, in which
 25 case the said alkyl or phenyl group may be substituted or unsubstituted, or alkoxy-terminated poly(alkylene oxide) groups having the formula

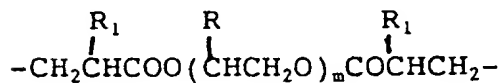
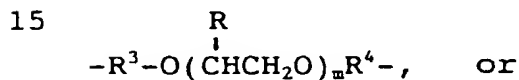


suitably methyl, R is hydrogen or a lower alkyl, R³ is a straight-chain or branched C₂ - C₆ alkyl, and m is 1...30,
 - partly bonds formed from the hydrogen or alkylene groups to other polymer chains in the elastomer, and

- 5 - possibly partly unreacted groups, such as hydrogen, vinyl or vinyl-terminated alkene, and
 - q is 1...3000.

5. The membrane or matrix according to Claim 4, characterized in that the free R' and R'' groups are a lower
 10 alkyl group, preferably methyl.

6. The membrane or matrix according to Claim 2 or 3, characterized in that the poly(alkylene oxide) groups are present in the elastomer in the form of poly(alkylene oxide) blocks having the formula



where R is hydrogen, a lower alkyl or phenyl, R₁ is hydrogen
 20 or a lower alkyl, R³ and R⁴ are the same or different and are straight-chain or branched C₂ - C₆ alkyl groups, and m is 1...30.

7. The membrane or matrix according to Claim 1, characterized in that the elastomer composition is made up of two
 25 elastomers interlaced one inside the other, in which case - the first elastomer comprises poly(alkylene oxide) groups, and that the poly(alkylene oxide) groups are present in the said elastomer as alkoxy-terminated grafts of polysiloxane units, or as blocks, in which case the said
 30 grafts or blocks are linked to the polysiloxane units by silicon-carbon bonds, or as a mixture of these forms, and

that

- the second elastomer is a siloxane-based elastomer.

8. The membrane or matrix according to Claim 7, characterized in that the second elastomer is a poly(dimethyl siloxane)-based elastomer which possibly comprises poly(alkylene oxide) groups.

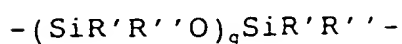
9. The membrane or matrix according to Claim 8, characterized in that the possible poly(alkylene oxide) groups of the second poly(dimethyl siloxane)-based elastomer are present in the form of alkoxy-terminated grafts of poly(dimethyl siloxane) units, or as blocks, the said grafts or blocks being linked to the poly(dimethyl siloxane) units by silicon-carbon bonds, or as a mixture of these forms.

10. The membrane or matrix according to Claim 1, characterized in that the elastomer composition is a blend which comprises

- a siloxane-based elastomer and
- a straight-chain polysiloxane copolymer which comprises poly(alkylene oxide) groups, in which case the poly(alkylene oxide) groups are present in the said polymer as alkoxy-terminated grafts of polysiloxane units, or as blocks, the said grafts or blocks being linked to the polysiloxane units by silicon-carbon bonds, or a mixture of these forms.

11. The membrane or matrix according to Claim 10, characterized in that the poly(alkylene oxide) groups are poly(ethylene oxide) groups (PEO groups).

12. The membrane or matrix according to Claim 10 or 11, characterized in that the formula of the polysiloxane groups is



where R' and R'' are the same or different and are a lower alkyl group, or a phenyl group, in which case the said alkyl or phenyl group may be substituted or unsubstituted, or alkoxy-terminated poly(alkylene oxide) groups having the formula

$$-R^3-O-\overset{\overset{R}{|}}{\text{CH}}-\text{CH}_2-\text{O})_m-\text{alk}$$
, where alk is a lower alkyl group, suitably methyl, R is hydrogen or a lower alkyl, R³ is a straight or branched C₂ - C₆ alkyl group, m is 1...30, and q is 1...3000.

13. The membrane or matrix according to Claim 12, characterized in that the free R' and R'' groups are lower alkyl groups, preferably methyl.

14. The membrane or matrix according to Claim 10 or 11, characterized in that the poly(alkylene oxide) groups are present in the straight-chain polysiloxane polymer in the form of poly(alkylene oxide) blocks having the formula

$$-R^3O-\overset{\overset{R}{|}}{\text{CH}}\text{CH}_2\text{O})_mR^4-$$
, or

$$-\text{CH}_2\overset{\overset{R_1}{|}}{\text{CH}}\text{COO}(\overset{\overset{R}{|}}{\text{CH}}\text{CH}_2\text{O})_m\text{CO}\overset{\overset{R_1}{|}}{\text{CH}}\text{CH}_2-$$

where R is hydrogen, a lower alkyl or phenyl, R₁ is hydrogen or a lower alkyl, R³ and R⁴ are the same or different and are straight-chain or branched C₂ - C₆ alkyl groups, and m is 1...30.

15. The membrane or matrix according to Claim 10, characterized in that the siloxane-based elastomer is made up of poly(dimethyl siloxane).

16. The membrane or matrix according to ~~any of~~ Claims 10 / 15, characterized in that the siloxane-based elastomer

comprises poly(alkylene oxide) groups, and that the poly(alkylene oxide) groups are present in the elastomer or polymer as alkoxy-terminated grafts of polysiloxane units, or as blocks, the said grafts or blocks being linked to the polysiloxane units by silicon-carbon bonds, or as a mixture of these forms.

17. The membrane or matrix according to ~~any of~~ Claims 1 ~~16~~, characterized in that it contains a filler, suitably silica.

18. A method for the preparation of a siloxane-based elastomer which comprises poly(alkylene oxide) groups and is intended for use in a membrane or matrix controlling the permeation rate of drugs, characterized in that

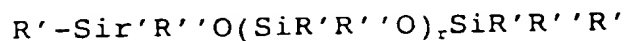
- a) a vinyl-functional polymer component and a hydride-functional component are crosslinked in the presence of a catalyst, or
b) a polymer component is crosslinked in the presence of a peroxide catalyst.

19. The method according to Claim 18, characterized in that the amounts of the vinyl-functional component and the hydride-functional component are selected so that the ratio of the molar amount of hydrides to the molar amount of double bonds is at minimum 1.

20. The method according to Claim 18 ~~or 19~~, characterized in that

I) the vinyl-functional polymer component is

a) a vinyl-functional polysiloxane having the formula



where R' and R'' are the same or different and are a lower alkyl group or a phenyl group, in which case the

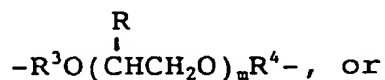
said alkyl or phenyl group may be substituted or unsubstituted, and where some of the substituents R' and/or R'' have been substituted for by vinyl groups, and r is 1...27000, or

- 5 b) an alkenyl terminated polysiloxane-based block copolymer having the formula

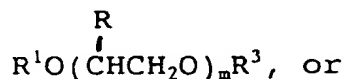
$T(AB)_xAT$ (I), where

10 $A = -(SiR'R''O)_qSiR'R''-$, where R' and R'' are the same or different and are a lower alkyl group or a phenyl group, in which case the said alkyl or phenyl group may be substituted or unsubstituted;

B is a poly(alkylene oxide) having the formula



15 $-CH_2\overset{\overset{R_1}{|}}{CH}COO(\overset{\overset{R}{|}}{CH}CH_2O)_mCO\overset{\overset{R_1}{|}}{CH}CH_2-$ and T is



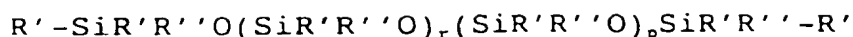
20 $CH_2=\overset{\overset{R_1}{|}}{C}COO(\overset{\overset{R}{|}}{CH}CH_2O)_mCO\overset{\overset{R_1}{|}}{CH}CH_2-$

where R is hydrogen, a lower alkyl or phenyl, R₁ is hydrogen or a lower alkyl, R³ and R⁴ are the same or different and are straight-chain or branched C₂ - C₆ alkylene groups, R¹ is a straight-chain or branched C₂ - C₆ alkenyl group, m is 1...30, q is 1...3000, and x is 0...100, or

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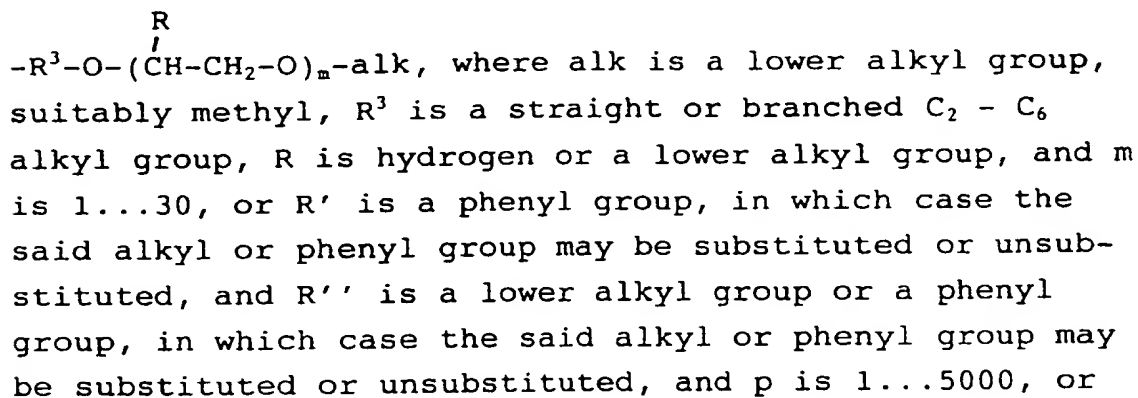
c) a vinyl-functional polysiloxane copolymer having the

formula

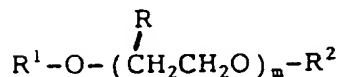


- where, in the first block, R' and R'' are the same or different and are a lower alkyl group, or a phenyl group, in which case the said alkyl or phenyl group may be substituted or unsubstituted, and where some of the substituents R' and/or R'' have been substituted for by vinyl groups, and r is 1...27000, and

- where, in the second block, R' is a lower alkyl group, or an alkoxy-terminated poly(alkylene oxide) group having the formula



d) α,ω -dialkenyl poly(alkylene oxide) having the formula



where R is hydrogen or a lower alkyl, R¹ and R² are the same or different straight-chain or branched C₂ - C₆ alkenyl groups, and m is 1...30, or

e) a blend of at least two of the above-mentioned components a) - d), and that

II) the hydride-functional component is

a) a hydride-functional siloxane which may be straight-chain, star shaped, branched or cyclic, or

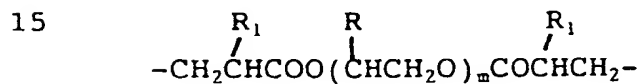
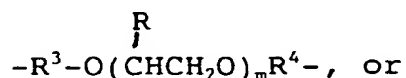
5 b) a hydride-terminated siloxane-based block copolymer having the formula

$T(BA)_x BT$ (II), where

$T = H-SiR'R''O(SiR'R''O)_q SiR'R''-$,

10 $A = -SiR'R''O(SiR'R''O)_q SiR'R''-$, where R' and R'' are the same or different and are a lower alkyl group or a phenyl group, in which case the said alkyl or phenyl group may be substituted or unsubstituted;

B is a poly(alkylene oxide) having the formula

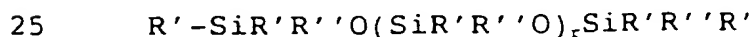


where R is hydrogen, a lower alkyl or phenyl, R_1 is hydrogen or a lower alkyl, R^3 and R^4 are the same or different and are straight-chain or branched $C_2 - C_6$ alkyl groups, m is 1...30, q is 1...3000, and x is 0...100, or

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c) a blend of the above-mentioned components a) and b).

21. The method according to Claim 20, characterized in that the hydride-functional siloxane copolymer is straight-chain, and that its formula is



where R' and R'' are the same or different and are a lower alkyl group or a phenyl group, in which case the said alkyl or phenyl group may be substituted or unsubstituted, and where some of the substituents R' and/or R'' have been substituted for by hydrogen, and r is 1...27000.

22. The method according to ~~any of Claims 18-21~~, characterized in that the vinyl-functional polymer component contains a filler, suitably silica.